



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/080,140	05/15/1998	PATRICIA A. BILLING-MEDEL	6105.US.P1	9090

23492 7590 01/08/2004

STEVEN F. WEINSTOCK
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/080,140

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

Karen A Canella

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 115-126 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 115-125 is/are rejected.
- 7) ☐ Claim(s) 126 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

1. Claims 74-114 have been canceled. Claims 115-126 have been added and are under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. Claims 117 and 126 are objected to because of the following informalities:

Claim 117 recites "of: of".

Claim 126 recites "degenerate codon equivalents of" sequences which are amino acid in nature. It is noted that "isolated polynucleotide sequences encoding a polypeptide" include degenerate codon sequences which encode said polypeptide. Amendment of the claim to read -- isolated polynucleotide sequences--- in the plural rather than in the singular, and the deletion of "and degenerate coding sequences..." is recommended. However, if applicant prefers, the claim could also read "...and degenerate codon equivalents encoding" SEQ ID NO: 25-29.

Appropriate correction is required.

4. Claims 115-125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 120 recites "a nucleic acid sequence that includes an open reading frame operably linked to a control sequence compatible with a desired host", wherein said nucleic acid sequence consists of SEQ ID NO:1-5, 7-12 and degenerate coding equivalents. The specification sets forth SEQ ID NO:1-10 as partial expressed sequences. One of skill in the art would not expect an expressed sequence to include a control sequence compatible with a desired host, as promoter sequences are not transcribed. Thus the limitation that said nucleic acid sequence must consist of SEQ ID NO:1-5, and 7-12 excludes the presence of an additional nucleic acid control sequence.

Claims 115, 117, 120, 122 and 123 recite "degenerate coding sequences thereof" without reference to a protein sequence which is being encoded. SEQ ID NO:1, 2, 7, 8, 9, 10, 11 and 12 are all polynucleotide sequences rather than polypeptide.

5. Claims 120 and 121 are rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young et al (US 5,856,136) or Reiter et al (US 6,267,960) for the same reasons of record given in the previous Office action. Claims 120 is drawn in part to a recombinant expression system comprising SEQ ID NO:4 and 5. Claim 121 is drawn to an isolated host cell transfected with the recombinant expression system of claim 120. Au-Young et al disclose purified polynucleotides comprising SEQ ID NO: 4 and 5 vectors, and kits thereof. Au-Young et al disclose Sequence 4 (nucleotides 1-207 and nucleotides 102-366) comprising the instant SEQ ID NO:4 and 5, respectively. Because the claimed expression system comprises a nucleic acid sequence that includes an open-reading frame, claim 120 reads on a nucleic acid sequence which comprises an open reading frame. Further, the instant specification discloses SEQ ID NO:4 and 5 as partial cDNA sequences, and as such, said partial DNA sequences are lacking a complete open reading frame. Thus, Au-Young et al disclose a polynucleotide of Sequence 4 comprising an open reading frame, expression vectors and host cells comprising said expression vectors which anticipate the instant claims.

Reiter et al disclose the purified polynucleotides of Sequence 1, vectors and kits thereof. Reiter et al disclose the polynucleotide comprising the instant SEQ ID NO:3 as residues 10-288 of Sequence 1, SEQ ID NO:4 as residues 12-218 of Sequence 1, and SEQ ID NO:5 as residues 113-377 of Sequence 1. Because the claimed expression system comprises a nucleic acid sequence that "includes" an open-reading frame, the claim reads on a nucleic acid sequence which comprises an open reading frame. Further, the instant specification discloses SEQ ID NO:3, 4 and 5 as partial cDNA sequences, and as such, said partial DNA sequences are lacking a complete open reading frame. Thus, the instant claims are anticipated by Sequence 1 of Reiter et al.

Applicant has provided claim 120 with the limitation of a recombinant expression system comprising a nucleic acid sequence that consists of a sequence selected from a group which includes SEQ ID NO:4 and 5 in order to overcome the prior rejection. However, it is noted that

Art Unit: 1642

claim 120 is rejected under 112, second paragraph because it appears that a nucleic acid sequence consisting expressed sequences is not compatible with a control sequence. It is also noted that claim 120 is drawn to an expression system comprising said nucleic acid sequence. Thus, when given the broadest reasonable interpretation, a recombinant expression system comprising the recited SEQ ID NO also reads on recombinant expression systems comprising larger nucleic acid sequences which encompass the instant SEQ ID NO:1-5, and 7-11.

6. Claims 120 and 121 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 120 and 121 are drawn to polynucleotide sequences comprising the sequence of SEQ ID NO:1, 2, 3, 4, 5, 7, 8, 9 and 10 for the reasons set forth in the rejections under 102(e) above.. The specification identifies said sequences as partial EST sequences (page 55, lines 1-12). The specification does not address whether the partial sequences comprise intron/exon splice junctions. When given the broadest reasonable interpretation, the claims can be interpreted as reading on genomic sequences, including any full length gene which comprises each of the sequence. Thus, each EST sequence represents a genus of polynucleotides.

The disclosure of a single species of a genus may provide adequate written description of the genus which the species disclosed is representative of the genus. The present claims encompass full length genes, cosmids and chromosomes comprising said genes. Eukaryotic chromosomes and genes are expected to comprise regulatory regions and untranslated intron regions. These regions are not disclosed by the specification. There is substantial variability among the species of polynucleotides encompassed by the genres because SEQ ID NO:1, 2, 3, 4, 5, 7, 8, 9 and 10 represent only a fragment of any full length gene or chromosome. Functional attributes such as coding capacity cannot be relied upon to distinguish partial sequence from complete genes and chromosomes because complete genes and chromosomes also would encode the sequence which was deduced from the analysis of the combined partial sequences (SEQ ID NO:25). One of skill in the art would reasonably conclude that applicant was not in possession of the genus which includes genomic DNA.

Art Unit: 1642


Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Karen A. Canella, Ph.D.

Primary Examiner, Art Unit 1642

01/02/04